SEP 16 2005

510(k) Summary

Applicant/Address

- BioBands Distributors, Inc., 30 Waterside Plaza, Suite 36K, New York, NY 10010

Contact Person/Telephone

- Georgia C. Ravitz, Counsel to BioBands Distributors, Inc., (PH) 202-857-8939; (FAX) 202-857-6395.

Preparation Date

- May 18, 2005

Device Trade Name

- BioBands

Classification Name

- Acu-pressure Device

Legally Marketed Predicate Devices

- K033268, "Sea-Band" wristband, by Sea-Band UK, Ltd; and K041877, Acu-Strap Motion Sickness Band, by Health Enterprises, Inc.

Device Description

- BioBands is an adjustable wristband that fits on either wrist. The device is composed from nylon and polyester fabric, and features a Velcro closure for easy adjustment. The BioBands wristband has a wooden bead or button sewn into the band's underside. When BioBands is worn by users, the wooden bead applies pressure to the P6 or "nei-kuan" acupuncture point. The gentle pressure applied by the bead to the P6 interrupts the signals that trigger nausea.

Intended Use

- BioBands is indicated for the relief of nausea (nausea may be experienced due to a variety of causes, including Travel (Motion Sickness), Pregnancy (Morning Sickness), Anesthesia (Post-Operative) or Chemotherapy.

Substantial Equivalence Summary

- BioBands is substantially equivalent to K033268, "Sea-Band" wristband, by Sea-Band UK, Ltd. BioBands is also substantially equivalent to K041877, Acu-Strap Motion Sickness Band, by Health Enterprises, Inc. Both of these devices are similarly constructed wristbands, that utilize the same principal of operation, and that are marketed for the same indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2005

BioBands Distributors, Inc.
c/o Mr. James H. Hartten
Regulatory Affairs Analyst
Arent Fox PLLC
1050 Connecticut Avenue, NW
Washington, DC 20036-5339

Re: K051397
Trade/Device Name: BioBands
Regulatory Class: Unclassified
Product Code: MVV
Dated: August 5, 2005
Received: August 5, 2005

Dear Mr. Hartten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051397

Device Name: BioBands

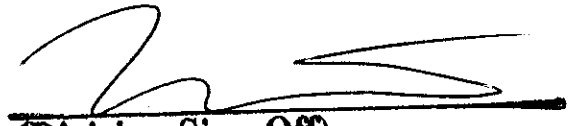
Indications for Use:

BioBands is indicated for the relief of nausea. Nausea may be experienced due to a variety of causes, including Travel (Motion Sickness), Pregnancy (Morning Sickness), Anesthesia (Post-Operative) or Chemotherapy.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051397